

REMARKS

Claim 12 has been amended so as to sharpen its definition of the invention relative to the applied references.

But it is believed that independent claim 1 is already amply definitive of the invention over the prior art, and so needs no amendment.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as unpatentable over LEVIN et al. in view of BURNS.

The present invention is concerned with providing a simple, low cost lancet having a spring return for the lancet which is relatively cheap to manufacture and simple to install and which removes the need for locating a return spring at the casing and the lancet during assembly thereof. This is achieved in the present invention by providing the lancet with integral undulating webs projecting down either side of the lancet body towards the location of the tip. It will be appreciated that this apparently simple concept solves a number of problems. Apart from the fact that the spring can be formed in one operation with the lancet body, it also provides the advantages that the webs, being integral with the lancet body, are effectively pre-anchored and so are already sufficiently located, leaving their forward ends free.

LEVIN et al. disclose a lancet having an outer casing, a drive head at one end and a needle at the other end. The

Official Action argues that it would have been obvious to modify LEVIN et al. to include a distal spring on the distal end of the device in order to aid in retracting the needle back into the casing after use. We dispute this, as the device of LEVIN et al. is clearly designed to use a recoil action of the main drive spring 50 to retract the needle tip 46 back into the body (see column 5, lines 4 to 6). To incorporate a return spring would be contrary to the teaching of LEVIN et al. Even if such a spring were to be incorporated in the device of LEVIN et al., this would be in the form of a conventional coil spring of the type used in several of the embodiments of BURNS. Still further, it is in line with such teaching that the spring would be located at both ends; in other words, the spring would bear at one end against the lancet body and at the other against the inside of the casing.

BURNS is primarily concerned with automatic retractable lancet assemblies which use two springs and in which the return spring operates independently and is dissociated from any movement of the driving spring. BURNS is concerned with ensuring that there is no requirement for balancing of spring forces. (See column 10, line 66 to column 11, line 4).

BURNS describes several different embodiments but in none of them is there provided a lancet body having integral webs projecting down both sides thereof. In the embodiments of Figures 1 to 9, an arrangement is provided in which, despite the

objectives of BURNS, the lancet piston 46 is acted upon by both the drive spring 26 and the return spring 28 when the lancet is at rest. In these embodiments, the spring 28 is described to be in a "substantially decompressed" condition at rest (column 4, lines 55 to 58) and maintains the lancet piston inside the housing (column 4, lines 50 to 52). Prior to release thereof, the thrust of the energized spring 26 urges sleeve 34 in the downward direction with the sleeve 34 having at its lower end arms 50 with projecting feet 52 that engage the top of the lancet piston (column 4, lines 59 to 66).

The combination of LEVIN et al. and BURNS would simply be a device that required dissociation of the drive spring during retraction and therefore would require some form of dissociation mechanism. Even if this were not the case, then the combination of LEVIN et al. and BURNS would result in a lancet body with a coil spring around the end thereof.

The embodiments of Figures 1 to 9 of BURNS employ a separate conventional coil spring. There is no motivation or teaching of the use of an integral spring and still less one with undulating form.

Turning now to the embodiments of Figures 10 to 14 (column 7, lines 1 to 9) there is described there the concept of a lancet device in which the lancet block 76, the secondary block 72 and the springs 74 and 75 are formed integrally from a plastic material. However, in this arrangement, the mechanical

arrangements of the springs are quite different from that of the present invention. In the embodiments of Figures 10 to 14, there is a "series" arrangement made up of the main drive spring 74 - block 72 - secondary spring 75 - lancet block. In the claimed invention there is a parallel arrangement with the main drive spring connected directly to the lancet block with the secondary springs (i.e. the undulating elements) being in parallel with this. There is an important difference in terms of thrust because in the claimed device the full thrust and travel of the drive spring will be transmitted directly to the lancet tip whereas in BURNS the thrust and travel are transmitted via the secondary spring which is likely to absorb some of the inertia/travel of the main spring. Furthermore, in the claimed device, the undulating webs act between the lancet and the main housing (but only during the retraction phase) whereas in BURNS, the equivalent (secondary) spring 75 acts between the blocks 72 and the lancet block 76, both of which are essentially floating relative to the housing.

If this concept were introduced into LEVIN et al., this would simply result in replacing the drive spring 24 and the lancet body 41 of LEVIN et al. with an integral series arrangement of a main drive spring 24, a rear lancet block 41a, an intervening spring, and a forward lancet block 41b which would not be the same mechanically and also would be more difficult to assemble.

Figures 15 to 18 of BURNS show a housing which provides an integral spring in the form of a coil spring and flat springs that act at different times on the lancet. In other words, the lancet is flung forward by the main drive spring and is released from the effect of the drive spring before it engages the retraction spring. There is also discussion of a coiled and folded spring in Figure 19. However, there is no discussion of an integral spring formed with the lancet body and certainly no hint or disclosure of a lancet body with integrally formed undulating webs.

The embodiments of Figures 20 to 22 of BURNS again provide separate leaf springs in the housing. Finally, Figures 23 to 28 provide yet another arrangement where there is a conventional coiled drive spring and a separate, conventional, coil retraction spring that act on the lancet piston. The lancet piston is free of the main drive spring before it compresses the retraction spring. It will therefore be seen that BURNS describes numerous different types of energizing and retraction springs, but none comes close to the simple and elegant solution of the present invention.

There is accordingly no motivation or teaching of the use of integral undulating webs, in LEVIN et al. or BURNS, considered separately or in combination. As a result, claim 1 recites subject matter that is unobvious in view of these references.

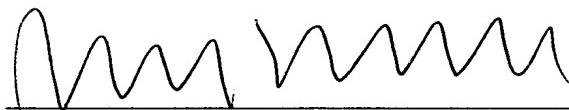
The same arguments of course apply to claim 12.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application has been placed in condition for allowance, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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